

Serial No.: 10/656,973
Filing Date: September 5, 2003
Group Art Unit: 3761
Examiner: Leslie R. Deak
Atty. Docket No.: 22719-47 (COD5023)

REMARKS

The pending Office Action addresses claims 1-27, rejecting claims 1-27.

Amendments to the Claims

Applicant amends dependent claim 9 to specify that the physiological characteristic measured by the sensor of the system is ventricular pressure. Support for this amendment can be found throughout the specification, for example, at page 10, lines 6-8. Applicant amends independent claim 17 to specify that the sensor element is a pressure sensor for detecting pressure variations within the ventricular cavity. Support for this amendment can be found throughout the specification, for example, at page 10, lines 6-8. Claims 19 and 21-23 have been amended to recite "pressure" in place of "volume." Support for these amendments can be found throughout the specification, for example, at page 10, lines 6-8. Applicant cancels claims 10-12. No new matter is added.

Rejection Pursuant to 35 U.S.C. §112

The Examiner rejects claims 9 and 17-27 pursuant to 35 U.S.C. §112, first paragraph, as failing to enable a sensor that measures the volume of the ventricular cavity. Applicant respectfully disagrees with the Examiner but has amended claims 9, 17, 19, and 21-23 to expedite prosecution. Applicant reserves the right to pursue the original claims at a later date.

Rejections Pursuant to 35 U.S.C. §102

The Examiner rejects claims 1-8 and 13-16 pursuant to 35 U.S.C. §102(e) as being anticipated by US 2003/0004495 A1 of Saul ("Saul 495"). Applicant respectfully disagrees.

Independent claim 1 recites a method of regulating cerebrospinal fluid flow in a hydrocephalus patient including the steps of providing an implantable shunt system, energizing the implantable shunt system with the system controller device, detecting a value of a physiological characteristic of the ventricular cavity, comparing the measured value with a predetermined target value, determining a desired resistance to achieve the predetermined target value, and adjusting a current resistance to achieve the desired resistance. Saul 495 fails to teach or suggest a method of regulating cerebrospinal fluid flow in a hydrocephalus patient whereby a

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value of a physiological characteristic of the ventricular cavity is detected by a sensor element. Saul 495 discloses a method for removing cerebral spinal fluid (CSF) from a CSF space of a patient at constant volumetric rates. Saul 495 does not teach implanting a sensor element in the ventricular cavity. Instead, Saul 495 uses a sensing device to detect the volume of flow *exiting* the CSF space over a period of time. (Saul 495 page 5, lines 22-28). Thus, Saul 495 does not teach or suggest detecting a physiological characteristic of the ventricular cavity, as required by independent claim 1.

Accordingly, independent claim 1, as well as claims 2-16, which depend directly or indirectly therefrom, distinguish over Saul 495 and represent allowable subject matter.

Rejection Pursuant to 35 U.S.C. §103

Claims 10-12

The Examiner rejects claims 10-12 pursuant to 35 U.S.C. §103(a) as being obvious over Saul 495 in view of US 2003/0032915 A1 of Saul ("Saul 915"). Applicant has canceled claims 10-12, thus obviating the Examiner's rejection.

Claims 9 and 17-27

The Examiner rejects claims 9 and 17-27 pursuant to 35 U.S.C. §103(a) as being obvious over Saul 915. The Examiner first asserts that "[w]hile the disclosure does not enable the use of a volume sensor, the disclosure does enable a device and method for controlling CSF shunting with a sensor that may calculate volume changes based on a pressure differential, as is known in the art." Thus, the Examiner argues that the claimed invention would have been obvious in view of the apparatus and method for controlling CSF drainage disclosed by Saul 915. Applicant respectfully disagrees.

Claim 9 depends from independent claim 1 which, as described above, recites a method of regulating cerebrospinal fluid flow in a hydrocephalus patient including the steps of providing an implantable shunt system, energizing the implantable shunt system with a system controller device, detecting a value of a physiological characteristic of the ventricular cavity, comparing the measured value with a predetermined target value, determining a desired resistance to achieve the predetermined target value, and adjusting a current resistance to achieve the desired resistance. The method includes energizing the system with a selectively operable external

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system controller device capable of communicating with the implantable shunt system. Saul 915 fails to teach or suggest a method of regulating cerebrospinal fluid flow in a hydrocephalus patient whereby the system is energized with an external system controller device. Moreover, there is no motivation to modify Saul 915 to include such a feature. Saul 915 discloses a method for lowering elevated intracranial pressure utilizing a fluid drainage controller which regulates the drainage of cerebral spinal fluid based on a cardiac or other transient component of the patient's intracranial pressure. The method of Saul 915 includes using a programmed controller to open a valve in response to increases in the transient component of the patient's intracranial pressure and close the valve in response to decreases in the transient component. (Saul 915 page 4, lines 21-25.) The controller is contained *within* the system and is programmed to automatically open or close the valve as the transient component of intracranial pressure increases or decreases. Thus, Saul 915 fails to teach or suggest the step of energizing the system with an external system controller device. Moreover, there is no motivation to modify Saul 915 to include an external controller. The method disclosed by Saul 915 includes continuously monitoring a patient's intracranial pressure in order to maintain a target pressure in the ventricles over a period of time. In contrast, the method of the claimed invention requires the patient or attending physician to energize the system using an external controller device. Thus, there is no motivation to modify a method aimed at continuous, automatic operation to include the intervening step of energizing. Accordingly, independent claim 1, as well as claims 2-16 which depend directly or indirectly therefrom, are not obvious in view of Saul 915 and therefore represent allowable subject matter.

Independent claim 17, as amended, recites an apparatus for regulating cerebrospinal fluid flow in a hydrocephalus patient including an implantable shunt system and a selectively operable external system controller device. The implantable shunt system includes an adjustable resistance valve for regulating the flow of cerebrospinal fluid into and out of a ventricular cavity of a patient and a pressure sensor for detecting pressure variations within the ventricular cavity. The selectively operable external system controller device is adapted to communicate with the implantable shunt system and is configured to effect an adjustment of the resistance of the valve when the device is applied to the patient. Saul 915 fails to teach or suggest an apparatus for regulating cerebrospinal fluid flow in a hydrocephalus patient including a selectively operable

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external system controller device for communicating with the system. Moreover, there is no motivation to modify Saul 915 to include such a feature. As explained above, Saul 915 discloses a system for lowering elevated intracranial pressure utilizing a fluid drainage controller contained *within* the system and programmed to automatically open or close the valve as the transient component of intracranial pressure increases or decreases. As previously discussed, there is no motivation to modify a system aimed at continuous, automatic operation to include a component that requires activation by the patient or attending physician. Accordingly, independent claim 17, as well as claims 18-27 which depend directly or indirectly therefrom, are not obvious in view of Saul 915 and therefore represent allowable subject matter.

Conclusion

In view of the above amendments and remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

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